

REMARKS

Status of the Claims

Claims 43-50, 52, 54-61, and 72-73 stand pending. Claims 51 and 53 were previously cancelled. Claims 62-71 and 74-75 have been previously withdrawn.

Summary of the Office Action

In the Final Office Action, Claims 43-50, 52, 54-61, and 72-73 stand rejected. Claims 43-50, 52, 54-61, and 72-73 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Pat. Pub. No. 2004/0039452 A1 to Bessler in view of U.S. Pat. No. 6,254,642 to Taylor. Claims 43-50, 52, 54-61, and 72-73 are rejected as unpatentable over U.S. Pat. Pub. No. 2004/0082963 A1 to Gannoe et al. in view of Taylor. Claim 52 is objected to for the "T-tag" limitation.

Rejections under 35 U.S.C. § 103(a)

Bessler in view of Taylor

The Examiner has not made a *Prima Facie* Case of Obviousness

As stated in the M.P.E.P. § 2142, in order to establish a *prima facie* case of obviousness, the references when combined must teach or suggest all of the claim limitations. The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. M.P.E.P. § 2142. Applicants respectfully disagree with the rejection, and submit that the Examiner has not made a *prima facie* case of obviousness because even when the references are combined, the combination does not teach the invention as claimed.

Moreover, because of the disparate objectives of the two references, one skilled in the art would have no reason to make the proposed combination.

Applicants' claimed invention recites, *inter alia*, a method in which the sleeve is both 1) attached without creating a serosal to serosal bond, and 2) attached using a tissue piercing anchor with a proximally facing surface which rests against the serosal surface.

Bessler discloses a gastric bypass "stent" 2 comprising a stent member 4 at the proximal end 6 of a tubular member 8 (paragraph [0018]). As the Examiner acknowledges in the Office Action, Bessler fails to teach or suggest tissue anchors "configured to have a transversely reduced

configuration for passing transmurally through the attachment site, and a transversely enlarged configuration after passing transmurally through the attachment site wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface.”

Taylor fails to make up for this deficiency. Taylor discloses an anti-reflux prosthesis 11 with a tissue anchor array 19 comprised of barbed spikes 25 for piercing and engaging the luminal wall of the esophagus. Applicants submit that the spikes 25 referred to by the Examiner in FIGS. 6A-6E of Taylor have the same configuration when passing through the luminal wall compared with after passing through the luminal wall (*see* Thompson Declaration at para. 6), and thus cannot function as a tissue anchor “configured to have a transversely reduced configuration for passing transmurally through the attachment site, and a transversely enlarged configuration after passing transmurally through the attachment site. . .” as recited in Claim 43.

Since the combination of references fails to teach or suggest each and every claim element, the Examiner has not made a *prima facie* case of obviousness. Thus, Applicants request that the rejection be withdrawn.

One of Ordinary Skill Would Have No Reason to Combine and Further Modify the References

In the Supreme Court’s recent decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ____ (2007), the Court repeatedly emphasized the value of determining if there is any “reason to combine” the various teachings in the art. The Court noted that “[a] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art.” (*KSR*, Syllabus, page 4 and page 14).¹ Thus, the Court has made it abundantly clear that some reason to combine the various elements must be present in order to establish a *prima facie* case of obviousness.

Applicants respectfully submit that one of skill in the art would have absolutely no reason to add transmural attachment anchors which are movable from a reduced cross section to an enlarged cross section to the disclosure of Bessler. *See* Thompson Declaration at para. 7. To the

¹ The Court also noted that “it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does.” (*KSR*, Syllabus, page 5; *see also*, page 15). Additionally, the Court noted that “inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” (*KSR*, page 15).

contrary, Bessler teaches a nonpuncturing attachment system, in the form of a self expandable or balloon expandable stent. By the time of Bessler's filing date, persons skilled in the medical device arts were familiar with a variety of tissue engaging attachment structures such as staples, sutures, and barbs. Yet Bessler failed to disclose any puncturing attachment structures, signaling clear preference for nonpuncturing attachment. Thus, the use of sharpened barbed spikes as disclosed in Taylor to secure Bessler's device would be contrary to Bessler's intent of providing a non-penetrating, less traumatic device for gastric bypass. *See id.*

Secondary Factors Support A Finding of Non-Obviousness

Secondary considerations must be considered in every case where they are presented. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983); *KSR International Co. v. Teleflex Inc.*, 550 U.S. ____ (2007). These include factors such as unexpected results, long-felt need, and failure of others. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986); *Graham v. John Deere*, 383 U.S. 1 (1966); *In re Sullivan*, No. 2006-1507 (Fed. Cir. 2007)(holding the PTO is obligated to consider applicant evidence of secondary consideration in cases where obviousness is at issue). A *prima facie* case of obviousness can also be rebutted if the applicant can show that the art in any material respect taught away from the claimed invention. *In re Haruna*, 249 F.3d 1327 (Fed. Cir. 2001).

Teaching Away

Bessler discloses that his device is advantageous as less traumatic than previous surgical techniques (paragraph [0005]). All disclosed embodiments of Bessler's device, involve an expandable stent 4 (Fig. 1) that does not penetrate any tissue walls to meet its objective of securing the ends of the device within the esophagus. In general, the teachings of Bessler would lead one of skill in the art in the direction of a non-penetrating anchoring system, such as a balloon expandable or self expanding stent as disclosed therein. Thus, Applicants submit that Bessler tends to teach away from the use of a penetrating tissue attachment, and that the use of Taylor's penetrating tissue fastener to secure Bessler's bypass stent would be contrary to Bessler's intent of providing a less traumatic device for gastric bypass. *See* Thompson Declaration at para. 7.

Failure of Others/Unexpected Results

Prior to the present invention, to Applicants' knowledge, all methods of attaching a device to an attachment site near or at the gastroesophageal junction in absence of esophageal cancer have generally resulted in failure. These methods have experienced a myriad of problems such as, for example, anchor migration, wall erosion, or rupture resulting in undesired device placement or explantation. Investigators have tried for years, without success, to achieve stable attachment of a variety of devices in the gastroesophageal region.

The assignee of the present application has expended a considerable amount of time, effort and money in an attempt to achieve a safe, stable fixation in the vicinity of the gastroesophageal junction. The stomach's response to the presence of implants is highly unpredictable, and it was completely unexpected that Applicants' claimed method using a transmural attachment having a transverse surface for contacting the serosa and which is transformable from a reduced configuration for transmural passage to an enlarged configuration for placing a footprint against the serosal surface would achieve stable fixation. Indeed, both animal and human trials performed thus far have shown the present claimed invention to be very effective in stably and securely attaching a bypass sleeve or attachment cuff to an attachment site near the gastroesophageal junction. See Thompson Declaration at para. 9. The success of Applicants' claimed methods and devices could not have been predicted from any of the teachings of Bessler, Taylor or Gannoe et al., raised by the Examiner as a basis of rejection.

Gannoe in view of Taylor

As noted above and stated in the M.P.E.P. § 2142, in order to establish a *prima facie* case of obviousness, the references when combined must teach or suggest all of the claim limitations. The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. M.P.E.P. § 2142. Applicants respectfully disagree with the rejection, and submit that the Examiner has not made a *prima facie* case of obviousness because even when the references are combined, the combination does not teach the invention as claimed.

The Examiner has not made a *Prima Facie* Case of Obviousness

Gannoe discloses methods and devices for creating a tissue ring such as in the upper stomach. As shown in Fig. 5E of Gannoe, use of the disclosed device results in acquiring tissue folds in a circumferential configuration within a hollow body organ (Abstract) with mucosal tissue on both external surfaces of the plication, and serosal tissue "sandwiched" in between the mucosal layers. This results in each end of the staple being attached to a mucosal surface of tissue. Attachment of a bypass conduit 113 at the GEJ at the tissue ring, as shown in Fig. 5E of Gannoe, results in each end of the staple resting against mucosa tissue of a circumferential tissue fold. Gannoe acknowledges the unsolved problem of how to attach a device in the stomach, and proposes as a solution bringing two serosal surfaces in contact with each other across a tissue fold. This seeks a permanent serosa to serosa scar tissue bond to reinforce and hold a tissue plication in place. Because, among other things, the serosa to serosa bond is not easily reversed, Applicants specifically avoid this approach and have expressly excluded this from the present claims.

As noted above, Taylor discloses an anti-reflux prosthesis 11 with a tissue anchor array 19 comprised of barbed spikes 25 for piercing and engaging the luminal wall of the esophagus. Applicants submit that the spikes 25 referred to by the Examiner in FIGS. 6A-6E of Taylor have the same configuration when passing through the luminal wall compared with after passing through the luminal wall (*see* Thompson Declaration at para. 6), and thus cannot function as a tissue anchor "configured to have a transversely reduced configuration for passing transmurally through the attachment site, and a transversely enlarged configuration after passing transmurally through the attachment site. . . " as recited in Claim 43. . "

Even assuming for the sake of argument that Gannoe and Taylor are combinable, a combination of Gannoe and Taylor would result in a gastric bypass stent wherein spikes 25 as disclosed in Taylor are driven through a mucosal-to-mucosal plication as taught by Gannoe. Such a combination will still facilitate serosal to serosal bonding via the plication, contrary to the recitation of Claim 43 of "attaching the proximal end [of the gastrointestinal sleeve] at the attachment site without creating a serosal to serosal bond." Since the combination of references fails to teach or suggest each and every claim element, the Examiner has not made a *prima facie* case of obviousness. Thus, Applicants request that the rejection be withdrawn.

One of Ordinary Skill Would Have No Reason to Combine and Further Modify the References

Even assuming arguendo the combination of Gannoe and Taylor could be further modified to arrive at the claimed invention, Applicants submit that one of ordinary skill in the art would have no reason to do so, e.g., attaching the proximal end of the gastrointestinal sleeve at an attachment site without creating a serosal to serosal bond. *See* Thompson Declaration at para. 8. As noted above and shown in Figs. 5A-5E of Gannoe, Gannoe teaches a mucosal to mucosal puncture of a plication, for the purpose of both reducing the diameter of the opening at the base of the esophagus and to permit serosa to serosa bonding to enable a lasting clinical result. This disclosure would not give one of ordinary skill in the art any reason to eliminate the plication which is contained in every embodiment disclosed in Gannoe, and instead use the method presently claimed, which would defeat Gannoe's objective of obtaining permanent serosa to serosa healing *See id.* Furthermore, an attachment step that does not result in serosal to serosal bonding as recited in Claim 43 would according to Gannoe not result in the acquisition of a sufficiently secure circumferential tissue fold and thus render Gannoe's device unsuitable for its purpose, and act as a disincentive to the combination proposed by the Examiner. *See* Thompson Declaration at para. 8; *Tec Air Inc. v. Denso Mfg. Michigan Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999)(if a proposed modification would render the prior art device being modified unsuitable for its intended purpose, the proposed modification would not have been obvious).

Secondary Factors Support A Finding of Non-Obviousness

Secondary considerations must be considered in every case where they are presented. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983); *KSR International Co. v. Teleflex Inc.*, 550 U.S. ____ (2007). These include factors such as unexpected results, long-felt need, and failure of others. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986); *Graham v. John Deere*, 383 U.S. 1 (1966); *In re Sullivan*, No. 2006-1507 (Fed. Cir. 2007)(holding the PTO is obligated to consider applicant evidence of secondary consideration in cases where obviousness is at issue). A *prima facie* case of obviousness can also be rebutted if the applicant can show that the art in any material respect taught away from the claimed invention. *In re Haruna*, 249 F.3d 1327 (Fed. Cir. 2001).

Teaching Away

As noted above, Gannoe teaches a mucosal to mucosal puncture of a plication, for the purpose of both reducing the diameter of the opening at the base of the esophagus and to permit serosa to serosa bonding to enable a lasting clinical result. This disclosure would not give one of ordinary skill in the art any reason to eliminate the plication which is of central importance to Gannoe and accordingly contained in every embodiment disclosed in Gannoe. Gannoe's objective of obtaining permanent serosa to serosa healing thus at least implicitly teaches away from the invention as claimed, which excludes serosa to serosa bonding as recited in Claim 43. *See* Thompson Declaration at para. 8. In general, the teachings of Gannoe would lead one of skill in the art in the direction of creating a plication for serosal-to-serosal bonding for permanent healing. Thus, Applicants submit that Gannoe tends to teach away from the use of Applicants' claimed transmural tissue attachment, which pursues the opposite objective of achieving attachment while leaving the native anatomy intact. Furthermore the use of Taylor's spikes through a non-plicated tissue wall to secure Gannoe's sleeve device would be contrary to Gannoe's intent of providing a plication for permanent serosa-to-serosa bonding. *See id.*

Failure of Others/Unexpected Results

As noted above, prior to the present invention, to Applicants' knowledge, all methods of attaching a device to an attachment site near or at the gastroesophageal junction with the exception perhaps of esophageal stents in certain cancer patients, have generally resulted in failure. *See* Thompson Declaration at para. 9. These methods have experienced a myriad of problems such as, for example, anchor migration, wall erosion, or rupture resulting in undesired device placement or explantation. *Id.* Applicants submit that one of ordinary skill in the art would be concerned that attempts to modify such devices would render them difficult or dangerous to remove from the gastrointestinal tract, and in fact it was unexpected that the claimed methods have been very effective in stably and securely attaching a device to an attachment site near the gastroesophageal junction, as evidenced by both animal and human trials performed thus far. *Id.*

In short, Applicants' surprising success in achieving attachment without substantial modification to the native tissue in the vicinity of the gastroesophageal junction was completely unpredictable to those of skill in the art familiar with the prior art references applied herein.

Dependent/Withdrawn Claims

Applicants note that Claims 44-50, 52, 54-61, and 72-73 depend from Claim 43 or claims depending thereof and recite all of the elements of Claim 43 as well as additional distinguishing features. Applicants submit that these claims are also in condition for allowance. Furthermore, withdrawn Claims 64-71 and 74-75 also depend from Claim 43 or claims depending thereof and recite all of the elements of Claim 43 as well as additional distinguishing features. Applicants request that these claims be reinstated into the application should Claim 43 be found allowable.

Claim Objections

The Examiner continues to object to Claim 52, finding that the recitation of a "T-tag" is overly broad, indefinite, unclear, and fails to particularly point out what Applicants consider the invention or any corresponding structure. Applicants respectfully note that the previously-submitted arguments regarding this objection do not appear to have been addressed by the Examiner, and have reproduced them again below for the Examiner's convenience.

Applicants disagree, and submit that a "T-tag" is both understood in the art, and is clearly defined in the disclosure. Furthermore, Applicants respectfully note that the Examiner has not yet addressed Applicants' arguments as set forth in previous responses and reproduced below, in support of withdrawal of the rejection.

For example, paragraph [0166] of Applicants' specification, states in part that a "T-tag is basically a cross member or "T" that is attached to an elongated member or tail at or near the mid-point of the T." As recited in paragraph [227], "the purpose of the T in a T-fastener is to distribute and resist the forces that could act to pull it through the tissue, in this case the gastric wall".

In general, the T-tag is one way of providing a serosal surface footprint which resists retraction through the stomach wall. The anchor passes transmurally from inside the tissue wall to outside the wall in a reduced cross-sectional configuration (e.g. by orienting the cross bar on

the T into parallel with the axis of penetration) and enlarges (e.g. by inclining the cross bar on the T into parallel with the serosal surface) following deployment. As recited in paragraph [0166], "T-tag fasteners are generally configured to flex at the juncture of the T and tail to allow delivery along the axis of the T through a minimal puncture diameter."

Applicants respectfully request that this objection be withdrawn.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicants wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
10/998,424	Apparatus and Methods for Treatment of Morbid Obesity	11/29/2004
11/025,364	Devices and Methods for Treating Morbid Obesity	12/29/2004
11/124,634	Devices and Methods for Attachment of an Endolumenal Gastrointestinal Implant	05/05/2005
11/431,040	Methods of Transmural Attachment in the Gastrointestinal System	05/09/2006
11/430,677	Attachment System for Transmural Attachment at the Gastroesophageal Junction	05/09/2006
11/431,054	Methods of Adjusting Therapy in a Patient Having an Endolumenal Bypass to Treat Obesity	05/09/2006
11/400,724	Devices and Methods for Endolumenal Gastrointestinal Bypass	04/07/2006

Serial Number	Title	Filed
11/430,275	Everting Gastrointestinal Sleeve	05/08/2006
11/430,278	Attachment Cuff for Gastrointestinal Implant	05/08/2006
11/430,274	Cuff and Sleeve System for Gastrointestinal Bypass	05/08/2006
11/429,934	Gastrointestinal Implant System	05/08/2006
11/548,605	Devices and Methods for Endolumenal Gastrointestinal Bypass	10/11/2006
10/903,255	Gastrointestinal Sleeve Device and Methods for Treatment of Morbid Obesity;	07/30/2004
11/236,212	Devices and Methods for Attachment of a Gastrointestinal Sleeve	09/27/2005
11/123,889	Devices and Methods for Gastric Surgery	05/06/2005
11/125,820	Suction Assisted Tissue Plication Device and Method of Use	05/10/2005
11/789,561	Methods and Devices for Gastrointestinal Stimulation	04/25/2007
11/861,156	Toposcopic Access and Delivery Devices	09/25/2007
11/861,187	Toposcopic Methods and Devices for Delivering an Elongate Sleeve Having Axially Compressed and Elongate Configurations	09/25/2007
11/861,172	Methods for Toposcopic Sleeve Delivery	09/25/2007
12/136,003	Methods and Devices for Intragastric Support of Functional or Prosthetic Gastrointestinal Devices	06/09/2008
12/135,989	Gastrointestinal Bypass Sleeve as an Adjunct to Bariatric Surgery	06/09/2008
12/137,473	Expandable Fastener System with Flower Petal-Shaped Retention Elements	06/11/2008
12/137,475	Endoscopic Delivery Devices and Methods	06/11/2008

Applicants direct the Examiner to the above tabulated references, and to their associated prosecution history, for the Examiner to consider, now and in the future, whether the subject matter claimed, as well as the associated prosecution history, may be relevant to the patentability of the present application (e.g., for reasons of obviousness-type double patenting). Applicants believe that the Examiner has access to the patents and pending applications and the file histories through the Patent Office (e.g., the IFW system). Accordingly, Applicants have not provided a copy of the references or the file histories, but would be happy to do so now or in the future, should the Examiner so request.

Application No.: 10/698,148
Filing Date: October 31, 2003

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance in view of the above remarks. Any remarks in support of patentability of one claim, however, should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claim and drawings in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the Applicants' attorney in order to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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